PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
FB/DM/BC45203		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP99/01894	17/03/1999	20/03/1998
International Patent Classification (IPC) or national classification and IPC C12N15/57		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01/10/1999	08.06.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Grosskopf, R Telephone No. +49 89 2399 8714

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/01894

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-38 as originally filed

Claims, No.:

1-28 as received on 02/03/2000 with letter of 02/03/2000

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 16-20,22-25,28.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 16-20,22-25,28 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15,21
	No:	Claims	26,27
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15,21,26,27
Industrial applicability (IA)	Yes:	Claims	1-15,21,26,27
	No:	Claims	

2. Citations and explanations

see separate sheet

Ad item III and V:

In the present application a nucleotide sequence (EST) has been isolated by using a (well-known) differential expression assay. For said sequence which has been arbitrarily denominated "CASB12" no function has been or could be determined.
In this context it has to be emphasised that an (undefined) "antigenic or immunogenic" property cannot be considered as being a "function". Moreover, it has to be mentioned that the experiments or passages in the description relating to corresponding experiments all are of totally speculative nature (supported by expressions like "can be..", "believed to be...", "will allow...")
Therefore, said sequence must be considered as being a "classical" EST sequence.

In view of the fact that no function has been determined, there is also no problem recognisable which is solved by said sequence (or even by sequences which have a certain degree of homology).
Therefore, the question whether said sequence fulfils the requirements of Article 33.3 (or 33.2), in principle, cannot be answered, respectively has to be denied.
Thus, claims which relate to the precisely defined nucleotide sequences or proteins lack an inventive activity.
Nevertheless, it must be notified that even the specific sequence claimed merely is a "further" equivalent to known sequences which has been obtained by a non-inventive method (said method being routinely used for characterising sequences which are (only) expressed in certain tissues or cancers; see example 1).

From a different point of view the isolation of said sequence is also obvious in view of e.g. D1 (EMBL database entry HS1237334; accession number AA436049; 1-JUNE-1997; Hillier et al.: 'WashU-NCI human EST project.' XP002110434) which discloses part of said sequence. The isolation of a larger part which "comprises" said sequence must be regarded as being devoid of an inventive activity.

Moreover, and again in view of the fact that no function could be determined, claims which relate to the (potential) use of said sequences must be considered

as being totally speculative (vaccine claims and use claims).
The same, in principle, applies for the claims directed to the protein since a protein has not (even) been prepared.

Moreover, claims which even try to broaden the scope are unclear, since, on the one hand, the skilled person has absolutely no hint in which region the 70% identity must be maintained.
On the other hand, a variation of the sequence without an aim (i.e. to retain "a" or the function (which?)) renders the claim meaningless.

Finally, claims which relate to SEQ ID NOs 3 and 4 are not novel over e.g. D1 (Biochim. et Biophys. Acta (1998), vol. 1399, pages 225-228) since they do not form part of the priority document.
If said sequences, in fact, were referred to in the priority document as SEQ ID No: 1 and 2, no difference could be seen e.g. between Claims 1 to 8 and Claim 26.
However, at least SEQ ID NO: 3 differs from SEQ ID NO: 1 since it has additional nucleotides and, thus, is not covered by the contents of the priority document.